CARDIOLINE®

ar600adv

user manual

CE 0470

English

This User Manual is prepared with the objective of giving the user all the information necessary to obtain the best use of the **CARDIOLINE® ar600adv**. Together with the traditional descriptions of the equipment's functions the following documentation will be found:

- Certificate of Guarantee

General information

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1 *Introduction*

ar600adv combines generous levels of performance in a portable electrocardiograph with all the features of reliability, modularity, versatility and upgradeability that characterise the latest generation of **CARDIOLINE®** electrocardiographs.
ar600adv is a portable electrocardiograph with dual power supply, (mains and rechargeable internal batteries), which in the basic configuration will:

- ✓ record an ECG exam in automatic, manual and timed mode;
- ✓ reproduce the ECG signal on 60 mm paper in various formats thanks to high resolution thermal printer: 1, 2, 2+R and 3 channels;
- ✓ store the most recent recording in automatic mode and print additional copies.

Thanks to the flexibility of the software used and to the infrared interface, the **ar600adv** can be adapted at any given moment to suit your individual requirements. The range of "*options*" offered is particularly generous and there are no restrictions or constraints, as the selection can be made either at the moment of purchase or later on at your clinic or surgery without having to interrupt day-to-day activity.
In just a few minutes your **ar600adv** can be equipped with:

- "memory option": storage of up to 20 full ECG exams, with no need to print out immediately on paper ("paper saving" mode);
- "ECG measurements option": automatic ECG parameter measurement program;
- "ECG signal interpreter option": a useful and dependable diagnostics support.
- "arrhythmia option": program enabling detection of arrhythmia events during continuous recording;
- "HRV analysis option": program enabling detection of variations in heart rate;
- "PC archive option": for saving the exam to archive stored in a personal computer running CARDIOLINE software. The data upload to the PC is made by use of the wireless "IR" interface; no direct connection to the PC is required.
- "PC-ECG option": for real time display of the twelve leads on your computer screen to allow management of patient medical records and archiving of exams in digital format using CARDIOLINE software. The software has an optional module for automatic interpretation of the ECG signal.

For more information on available options, contact your selected dealer.
CONGRATULATIONS ON YOUR PURCHASE. Your new computerised electrocardiograph CARDIOLINE® has been designed and built in compliance with the applicable regulations in force at the time when et medical devices SpA, Cavareno (Trento) - ITALY drew up this manual. et medical devices operates in accordance with the requirements for quality management systems defined by EN ISO 9001: 2000 and EN ISO 13485:

2003 standards. The system is covered by a Nemko Certification AS (Cert. N. 800278). Your new electrocardiograph has also been built in compliance with the Medical Device Directive 93/42/EEC and is therefore marked by the relevant CE0470 mark.

1.1 How to read the manual

In order to ensure the **CARDIOLINE® ar600adv** is operated in a safe and correct manner, and to appreciate its ease of use and high reliability, **the user instructions must be read carefully**.

This documentation describes the functions of your electrocardiograph including those provided by all the possible "options" available. It is therefore possible that some of the functions described may not be present in the model you have purchased. For details of the options, consult the "firmware configuration" chart which accompanies each individual appliance.

This symbol allows you to identify the functions **not** provided on all models, which must be requested specifically at the time of purchase.

This symbol allows you to identify the functional, behavioural and operational aspects that may be conditioned by the type of configuration selected during the step of *"Preparation for use: the menu"*.

When a given key is depicted in the body of a sentence or a paragraph, *press* the corresponding key on the device to perform the action.

The structure of this manual allows you to approach the use of the electrocardiograph according to your level of knowledge. If you have already had experience with **CARDIOLINE®** equipment, the initial fast-track part of each paragraph will allow you to begin working immediately. In the continuation of the paragraph, on the other hand, the single aspects of operation are discussed in more depth.

The manual gives detailed information on the use of the model **ar600adv** in traditional ECG procedures, and an introduction to the use of particular functionalities involving interaction with software and a Personal Computer. For instructions on the use of the software applications for Personal Computer, consult the special online guides.

The quick guide to the electrocardiograph (at power-up the display shows the message " ? Press 1 " to obtain the printout) sums up the operations linked to the single commands presented in the manual.

Further information and clarifications can be requested directly from:
***CARDIOLINE®** - Product Support*
Strada Rivoltana Nuova, 53, I - 20060 Vignate (MI) ITALIA
e-mail: et.service@etmed.biz
tel. +39 02 95 05 181 fax: +39 02 95 66 013

1.2 Information and recommendations relating to safe use

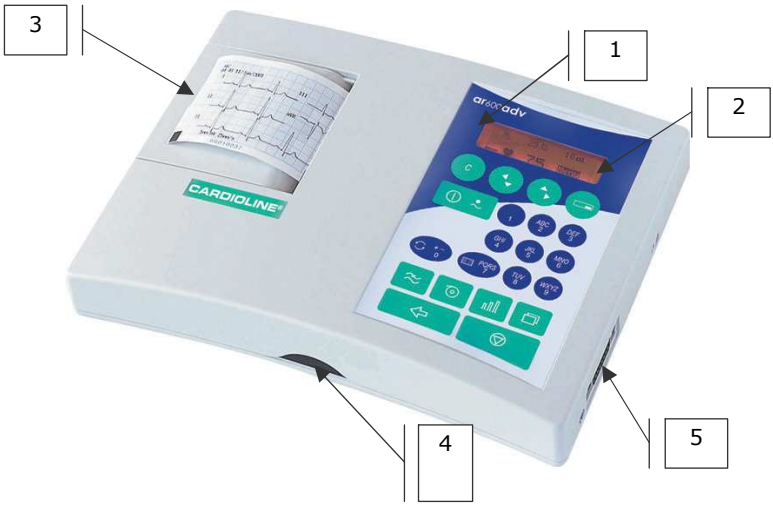
- Safety information and recommendations.
- The device is equipped with a set of standard accessories. For reasons of safety, reliability and conformity with the Medical Devices Directive 93/42/EEC, use only original accessories or accessories approved by the manufacturer.
- The device is equipped with a special long-life thermal head writing system, which allows maximum writing precision. To avoid frequent and costly replacements and repairs, always use the original paper or paper approved by the manufacturer. The manufacturer will not accept liability for any damage to the device or any other adverse effect caused by the use of unsuitable paper.
- Do not subject the device to impact or excessive vibrations.
- Do not allow liquids to penetrate inside the device. If this should accidentally occur, have the device tested by an Authorized Assistance Centre to verify its functional efficiency, before using it again.
- Make sure that the value of the supply voltage corresponds to that indicated on the data plate of the device.
- If you are using the device in connection with others, ensure that: all connections are made by skilled persons; all connections comply with safety regulations; all other devices connected respond likewise to regulations. Non-compliance with regulations can cause physical harm to the patient connected and to the person operating the device. Should it be difficult to obtain the necessary information for assessing the risk of the individual connections, apply directly to the manufacturers concerned or avoid making the connections.
- In the event of other equipment being connected directly or indirectly to the patient, check for the possible risks caused by the sum of the leakage currents on the body of the patient.
- The device is protected against defibrillation discharges in accordance with IEC standard 601-1-25; to ensure that the signal is restored, use only original electrodes or electrodes responding to IEC and AAMI standards.
- If an electrosurgical scalpel is in use, the patient cable should be disconnected from the device.
- At all events, when defibrillators or high-frequency surgical devices are being used at the same time, it is essential to take the greatest care. If there is any doubt when such devices are in use, disconnect the patient from the electrocardiograph temporarily.
- The device recognizes the impulses generated by a pacemaker and does not interfere with its operation, as prescribed by standards in use at the time of drafting this manual.
- Avoid exposing the equipment to extreme temperatures, excessive dust or dirt, and very salty or damp environments; observe the ambient conditions described in detail under the "*Technical specifications*" heading.

- Periodically check the efficiency of all accessories and of the device itself. Use the built-in test function to make a first check on the efficiency of the device. Contact the Authorized Assistance Centre whenever the device seems to be operating irregularly.
- To prolong the life of your device, have it checked periodically by an Authorized Assistance Centre.
- **Caution:** do not use the electrocardiograph for intracardiac applications or for monitoring activities in the operating theatre!
- **Caution:** do not use the device in the presence of anaesthetics or volatile gases!
- **Caution:** devices for medical applications must be used only by persons who by virtue of training or practical experience are able to ensure maximum safety and effectiveness in operation. Operators must in any event read this manual carefully and familiarise themselves with the instrument before using it on a patient.
- **Caution:** the indications obtained using automatic interpreting programs or other diagnostic aids must be reviewed and countersigned by a qualified medical person!
- **Caution:** use only original "battery chargers" as indicated alongside the connector and in the "*Accessories supplied*" heading. The original battery charger ensures the electrical isolation of the patient and the operator, guaranteeing essential conditions of safety. *Do not use* replacement accessories that have not been approved by the manufacturer.
- **Caution:** the device is provided with an IR interface for the transfer of data to other devices. The IR interface must not be masked , even accidentally, as this will adversely affect its capability and its operation, interrupting and preventing the correct flow of data.
- The manufacturer will acknowledge liability for the safety, reliability and functional efficiency of the device only if:
  - modifications and repairs are performed by the manufacturer or by an Authorized Assistance Centre;
  - the a.c. mains power supply of the building responds to current regulations;
  - the device is operated according to user instructions;
  - any accessories in use are those approved by the manufacturer.

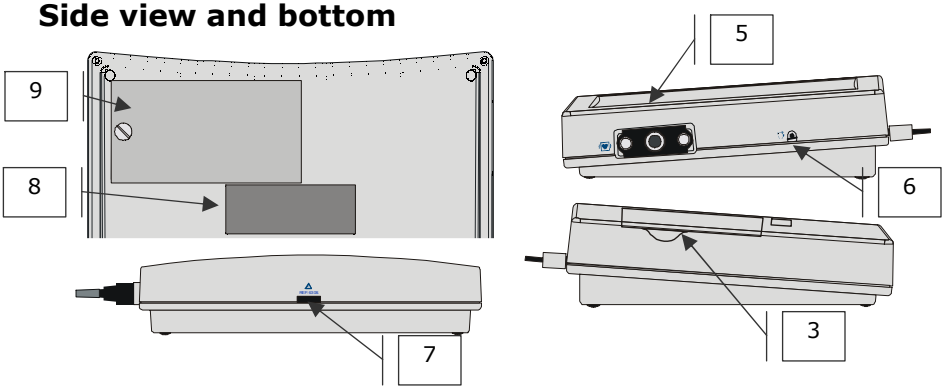
1.3 The electrocardiograph

In order to simplify the installation and the use of your electrocardiograph, it is recommended that you become familiar with the component parts and with the logic of its operation.

Front view

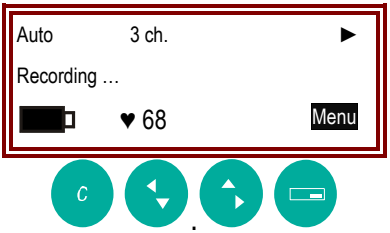


Side view and bottom



Parts, symbols and controls

1. display: for the management of operations and patient data.

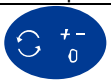
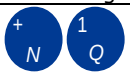


In normal operating mode:

- line 1: information relating to selected recording parameters;
- line 2: operating information and error messages;
- line 3: indication of battery charge status; heart rate; menu;
- ▲▼◄► these indicate the presence of additional information or menu options.
- C cancel operation, delete text, return to previous menu.
- . view menus and information.
- Access and select menu. Executes the action highlighted at the bottom right of the display (e.g. Select).

2. The keyboard.

Key Function	Display messages & symbols/ associated Leds	
On / Off	●~	- LED alight: device connected to a.c. power supply; internal batteries charging
		- "full" symbol: batteries charged - "part-empty" symbol: charge level of batteries lower than 30% - "empty" symbol: internal batteries flat; the device must be connected to the a.c. supply and recharged

start selected operating mode	⚠	- indicated electrodes not connected or insufficient contact; saturation
interrupt current operation; stop		
 Select operating mode		
Select print format	Automatic mode: 1, 2, 3, 3+R Manual mode: 1, 2, 3	
a.c. mains and muscle interference filter		- filter on
selection of paper speed	25	- paper speed 25 mm/s
	50	paper speed 50 mm/s
Selection of recording sensitivity		- automatic sensitivity: the device optimizes the ratio between n° channels and available space
	5	- sensitivity 5 mm/mV
	10	- sensitivity 10 mm/mV
	20	- sensitivity 20 mm/mV
copy last recording		
 alphanumeric keys		

3. Paper compartment cover.

4. IR interface.

5. Connector for CF type patient cable protected from defibrillation as indicated by the symbol .

6. "Reset" key : allows normal operating conditions to be restored in the event of an error that cannot be managed using the keys.

7. "Battery charger" connector.

8. Data plate. Always refer to the data indicated when communicating with Authorized Assistance Centres,

9. Battery compartment cover.

2 Installation and initial preparation

This section describes the operations to be performed prior to using your new **CARDIOLINE® ar600adv** electrocardiograph. Suggestions are given for "*selecting the best installation site*", along with reminders of "*recommendations for safe use in conformity with current statutory regulations*". Also introduced are the operations involved in preparing the electrocardiograph for use, such as "*loading the thermal paper*", "*power supply; control and management of the rechargeable internal batteries*", "*switching on and off*", "*menu*", "*setup*".

2.1 Selection of the installation site

The electrocardiograph is in conformity with European directives on electromagnetic compatibility. The absence of emissions damaging to radio and telecommunications transmissions is therefore assured, as also is protection from interference emitted by other systems and equipment. Nevertheless, in order to protect your device from other equipment not in conformity with the aforementioned directives:

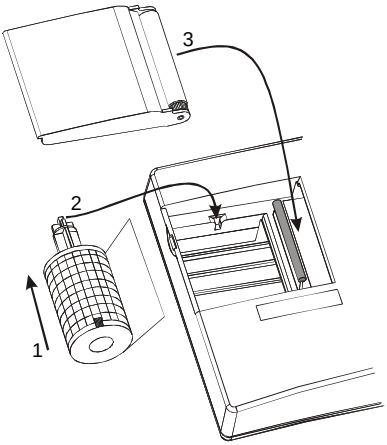
- avoid the use of cellular telephones in the vicinity;
- place the electrocardiograph as far as possible from electrical power lines or from sources of static electricity. The ECG signal can in fact be disturbed if the electrocardiograph is situated close to sources of high voltage or power lines;
- avoid placing the electrocardiograph close to other diagnostic or therapeutic equipment (e.g. X-ray machines, ultrasound machines, electrically operated beds, etc.) that could be a source of excessive interference and ECG signal distortion;
- if it is impossible to distance the electrocardiograph far enough from other electrical equipment, turn this equipment off during ECG recordings.

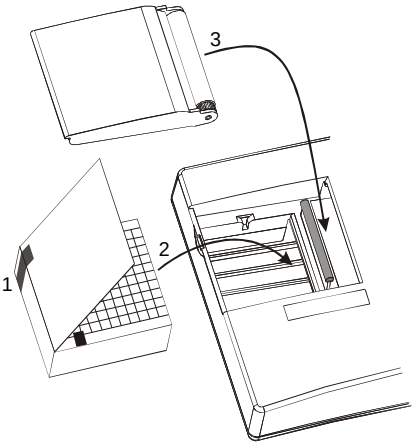
Also, to avoid ambient conditioning when conducting an exam:

- record in a room where the temperature is between 20 and 25 °C. This measure will prevent the patient from shivering, which would increase the incidence of muscle tremor;
- record the ECG using battery power, with the device unplugged from the a.c. power supply. This will eliminate the possibility of the recorded ECG signal being affected by a.c. mains disturbances.

2.2 Loading the thermal paper

CARDIOLINE® ar600adv will reproduce the ECG signal on thermal paper procured either in rolls or in packs. No special setup procedure is required. This sections gives the instructions for the correct loading of both types of paper.





If using rolls of paper:

a. Using a coin or similar implement, open the paper compartment and remove the "roll guide" hub. *If replacing a depleted roll, recover the hub before throwing away the core of the previous roll.*

b. Slot the hub into a new roll of paper (1) and locate in the paper compartment, positioning the pins in the sockets (2). *Ensure that the black mark on the paper is on the lower part of the roll*.

c. Close the cover, positioning the paper between the rubber roller and the casing of the device (3).

If using packs of paper:

a. Using a coin or similar implement, open the paper compartment and remove the "roll guide" hub. *To ensure the hub will not be lost accidentally, store it in a safe place.*

b. Prepare a new pack (1) and position it in the compartment (2). *Ensure that the red mark on the paper is at the top left of the pack*.

c. Close the cover, positioning the paper between the rubber roller and the casing of the device (3).

Warning: *use only original thermal paper or paper approved by the manufacturer. The use of paper that does not respond to the manufacturer's specifications could jeopardise the correct operation of the device.*

2.3 Power supply; control and management of the rechargeable batteries

Your electrocardiograph is characterised by a dual power supply system: a.c. mains and NiMh rechargeable internal batteries.

The rechargeable batteries come as a pack of 4+4 elements housed in the

battery compartment on the bottom of the device, and are protected against short circuits.

Warning: *before using the device, a full battery charge cycle must be carried out!*

To connect the electrocardiograph to the a.c. power supply, plug the "battery charger" (provided) into the connector

on the back of the device. The "battery charger" is protected against short circuits by an internal fuse (not replaceable) and against overheating.

Caution: *before connecting the electrocardiograph to the a.c. supply, make certain that the input voltage indicated on the battery charger is the same as the mains voltage.*

Caution: *the battery charger is a class II power supply and therefore does not require an earth connection.*

Caution: *when the device is connected to the a.c. supply, the internal batteries are recharged automatically, even during use.*

To gain maximum benefit from the characteristics of the dual power supply system, follow the indications given below.

Recharging the batteries

The batteries must be recharged when the charge indicator symbol appears part-empty : the reserve charge is lower than 30%.

Connect the electrocardiograph to the a.c. mains supply: Led lit. The full recharge cycle takes about 14 hours.

For longer life, the batteries should be allowed to run down and recharged completely at least every two months.

A complete recharge allows the recording of up to 500 complete ECGs (automatic recording mode, 3 channel print format, speed 25 mm/s).

If the batteries should be completely discharged (symbol), it is still possible to make an ECG recording by connecting the device to the a.c. mains supply.

The average life of the batteries is more than 300 complete discharge/recharge cycles.

Warning: *do not dispose of spent batteries as ordinary refuse or litter. Use only original batteries provide from the manufacturer. The battery lifetime is approximately one year.*

Battery charger: precautions for use

- The "battery charger" can be damaged if dropped, struck or tampered with.
- Do not immerse the "battery charger" in water or other liquids. Do not place the battery charger on or near sources of heat when in use.
- Do not damage or tamper with the cables for connection to the mains and to the electrocardiograph.
- Connect the "battery charger" to the electrocardiograph only by means of the connector provided.
- Use the "battery charger" only at the specified mains voltage. If the "battery charger" provided is not compatible with your a.c. mains supply, ask the nearest Authorized Assistance Center for a suitable model.

2.4 How to switch on the electrocardiograph

for at least two seconds.

The display lights up. When the device has powered up, the current settings will be displayed and it is possible to proceed.

Caution: *if the symbols* *and* *are displayed, internal power is insufficient and the batteries must therefore be recharged by connecting the device to the mains (see heading* "Power supply; ..."*). The batteries will recharge even if the device is in use.*

2.5 How to switch off the electrocardiograph

.

The display goes blank. The last ECG recorded, if any, and the relative settings, remain stored in the memory.

Caution: *switching off is not enabled 1. during the transmission of an ECG to a PC; 2. during the self-test routine; 3. if "setup" mode is active. In these cases, first stop the device* *and then switch off.*

Auto power off

To conserve the battery charge, the electrocardiograph is provided with an auto power off function that will activate automatically, depending on the amount of power still available and on the operating mode selected. *The procedure is activated only after the current operation has been completed*.

- After 10 min. have elapsed without any key being pressed: reserve power > 30%.

- After 1 min. has elapsed without any key being pressed: reserve power between 15 and 30% .
- After 10 sec. have elapsed without any key being pressed: reserve power < 15% .

If the auto power off function is activated, last ECG recorded, if any, and the relative settings, will be held in the memory.

Auto power off is inhibited if:
- A recording is in progress in ECG Autotimer mode;
- a recording is in progress in PC-ECG mode;
- during the self-test routine;
- during "setup".

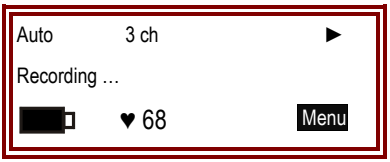
3 Preparation for use: the menu

Navigating within the menu of your **ar600adv**, there are options for intuitive personalization of the operating modes using the dedicated display keys.

To ensure your electrocardiograph can be operated taking advantage of its simplicity and versatility of use to the maximum, it is advisable to select the preferred setup before the first recording is made.

3.1 How to access the menu

From the main page:



- to display the menu.
- to scroll through the menu items.
- to access the lower level menu or make a selection. Executes the action highlighted at the bottom right of the display (e.g. Select).
- to return to the previous level.

3.2 Structure of the menu

The menu is organized in five sections: "Operating mode"; "Print format"; "ECG archive"; "Settings" and "Tools". The following tree layout of the menu illustrates the different levels of exploration possible, and the features that can be selected. Details on the single items are given in subsequent headings.

- *Operating mode*
  - ECG Automatic
  - ECG Manual
  - Paper Saving ☑
  - PC ECG ☑

- ECG autotimer
- Arrhythmia Monitor ☑
- HRV analysis ☑

➢ *Print format*
- 1 channel
- 2 channels
- 3 channels
- 2+R
  - Rhythm lead selection

➢ *ECG archive* ☑
- *View*
  - PC archive
  - Print
  - Delete
- PC archive
- Print list
- Empty

➢ *Settings*
- Use profile
  - Patient data management
    - Always prompt
    - Data only
    - None
  - Leads sequence
    - Standard
    - Cabrera
  - No. pages Auto
    - 1 page
    - 2 pages
  - Configure analysis ☑
    - ECG measurements
      - Summary
      - ST amplitudes
      - Representative cycles
    - ECG interpretation
      - Summary
      - Rhythm
      - Interpretation
      - Parameters
      - Representative cycles
    - None
  - PC archive ☑
    - Hard copy
    - Copy to PC
  - Archive management
    - Save
      - Automatic
      - Prompt

- None
- Deleting
  - Manual
  - Automatic
- Analisi HRV
  - Duration: x
  - Lead
- Autotimer
  - Nr. intervals xxx
  - Duration of intervals
  - Print format
    - 12 leads
    - 3 leads
      - Leads selection
- Arrhythmia mode
  - RR Advance
  - RR Delay
  - Print Advance
  - Print Delay
  - Arrhythmia Monitor

- General
  - User name
  - Date \ Time
  - Mains filter
    - 50 Hz
    - 60 Hz
  - Display
    - Illumination
    - Contrast

- *Tools*
  - About
  - Self-test
    - User
      - Display
      - Keyboard
      - Printer
      - Memory
      - About
    - Service
      - Not Available

3.3 Menu-activated operation and personalization of the electrocardiograph

Listed below are the operating and configuration details associated with the single items of the menu. To operate the menu refer to the heading "*How to access the menu*".

The "Operating mode"

Different methods of recording are available. The selected mode is indicated in the main page of the display at the top left.

It's possible to modify the selected operating mode before the recording, using the dedicated keys (see "Selection of recording characteristics: operating mode, print format, speed, sensitivity, filters").

Options / Actions available	Description
ECG automatic	All of the ECG leads are recorded simultaneously (10 seconds). The signal printed on paper refers to the same time period and is stored in the memory.
ECG manual	The selected leads are recorded and printed on paper. The signal is recorded in real time, i.e. acquisition and reproduction of the trace are simultaneous.
ECG Autotimer	ECGs are recorded automatically at user-defined intervals in Settings menu.
☑ Paper saving	The ECG trace is recorded and saved without any hard copy of the signal generated. The steps and the quality of the recording are monitored through messages in the display. Thereafter, the recording can be printed or saved to PC archive. Feature associated with "memory" option.
☑ Arrhythmia Monitor	The ECG signal is acquired in continuous mode and then printed in compressed format. Arrhythmia events, if any, are indicated on the trace.
☑ HRV analysis	The signal is acquired and then reprocessed, indicating the parameters and trends of the variation in heart rate.
☑ PC ECG	The twelve ECG leads are displayed in real time on your Computer screen where, thanks to the CARDIOLINE software, it is possible to perform all the ECG recording operations.

"Print format"

There are four print formats available.

The format selected will be applied to all recordings made in manual and automatic mode, and in twelve leads autotimer.

It's possible to modify the print format before the recording, using the dedicated keys (see "Selection of recording characteristics: operating mode, print format, speed, sensitivity, filters").

Options / Actions available	Description
1 channel	One ECG lead per page printed.
2 channels	Two ECG leads per page printed.
3 channels	Three ECG leads per page printed. To avoid any "overlapping" of leads, it is advisable to select automatic recording sensitivity.

2+R	Three-channel print of 2,5 sec duration for the 12 leads, plus 10 seconds continuous for the lead selected as cardiac rhythm reference. The rhythm lead is user-selectable. Print format available for automatic recordings only. To avoid any "overlapping" of leads, it is advisable to select automatic recording sensitivity.

The "ECG archive" ☑

The menu allows the main archive management functions to be operated.

Options / Actions available	Description
View	Displays the ECG list contained in the archive. Scroll the list and select an exam/patient. The user can now: 1. Archive the selected exam to a Personal Computer *("ArchPC");* 2. Print the selected example ("*Print*"); *3.* Delete the exam selected ("*Delete*").
PC archive	Transfers and archives all stored exams to PC.
Print list	Prints the list of exams currently in the memory.
Empty	Deletes all exams held in the memory. A confirmation message is displayed.

"Settings"

The "settings" menu allows different users to configure the functions of the electrocardiograph as best suits their individual working methods. Configurable properties are grouped together into two menus: "Use profile" and "General".

"Use profile"

Options / Actions available	Description
Patient data management	The method of managing patient data can be selected by the user. Three options are available: *1. Automatic prompt before every recording ("Always prompt". Not available in "PC ECG" mode);* 2. Automatic prompt before every recording for essential data only: sex and date of birth ("Status only"); *3. No patient data management ("None"):* the patient card is not visualized.

Leads sequence	The sequence in which leads are printed can be selected by the user. Besides changing the order in which the ECG leads are reproduced on paper, selection also influences the rhythm lead selection menu. Two options are available: *1. Standard;* *2. Cabrera.*
Number of pages in automatic mode	The user can select the length of the signal to be represented on paper during automatic recordings, indicating the number of pages to be used. Two options are available: *1. one page per lead or group of leads (if a multi channel format has been selected;* *2. two pages per lead or group of leads (if a multi channel format has been selected).*
☑ Analysis configuration	The user can select the type of processing to be performed on an ECG trace acquired in automatic mode. Selection influences the type of document that will be printed. There are two configuration menus available, linked to the two automatic processing options: "ECG measurements" and "ECG Interpretation". Processing can also be disabled altogether by selecting "None". ➢ "ECG measurements". o "Summary": this is the minimum reporting level, which cannot be deselected. Occupying two pages, it shows: date and time of recording, patient data, notes field, computed ECG parameters with representative reference cycle. o "ST amplitudes": ST depression values relative to the twelve leads, printed on one page of the table. o "Representative cycles": representative cycles relative to the twelve leads, printed on two pages. ➢ "ECG Interpretation". o "Summary": this is the minimum reporting level, which cannot be deselected. It shows: date and time of recording, patient data, notes field, computed ECG parameters, frontal vector ???, indication of normality. o "Rhythm analysis": printout of cardiac rhythm strip and relative diagnosis. o "Diagnosis": processing and printout of ECG interpretation. In particular: atrial diagnosis, repolarization changes, atrial blocks, QRS-T evaluation. o "Remarks": printout of items considered in evaluation of recording quality (e.g. state of electrodes, disturbances, etc). o "Measurements": printout of complete ECG measurements table. o "Representative cycles": printout of representative cycles relative to the twelve leads,
☑ PC archive	Using the PC archive function, in association with CARDIOLINE software, a trace recorded and stored in automatic mode can be transferred to a computer. The functionality of the copy key is adapted according to the selection. 1. "Copy to PC": pressing the copy key, the last recording made automatically is transferred to the computer. 2. "Hard copy": pressing the copy key, the last recording made is printed on paper.

☑ Archive management	The user can select the method of saving ECG traces and verifying the status of the memory. ➢ "Save" o "Automatic": the recording is saved automatically at the end of acquisition, with no action on the part of the operator. The progress of the operation is indicated by display messages: "Saving …" and "ECG in archive". o "Prompt": at the end of the recording, the display will prompt the operator whether to save or not: "Save ECG?". Press OK to proceed. o "None": save is disabled. ➢ "Deleting" o "Manual": it is possible to delete a file through function "Delete" in menu "view" in "ECG archive." o "Automatic": auto-delete all files in archive after transmission has been successfully done (PC archive option must be installed).
HRV Analysis	The user can set: the duration of the test (from 1 to 5 minutes) and the reference lead for the analysis.
ECG Autotimer	The user can set: the number of recordings (intervals); the duration of the intervals (the time elapsing between one recording and the next); the number of leads printed: twelve (programmed format), three (selectable).
Arrhythmia	The user can set: - the RR advance (in percentage); - the RR delay (in percentage); - the Print Advance: how many seconds of signal to be printed as reference normal ECG before the first event (min 2 sec. max 10 sec.); - the Print Delay: how many seconds of normal ECG after the last event (min 2 sec. max 10 sec.); - Arrhythmia monitor: enable the printout of the abnormal ECG during the test.

"General"

Options / Actions available	Description
User name	The user can enter personal identification details that will appear on all documents printed out. Available space 30 characters.
Date \ Time	This brings up the date and time programming pages. Values are entered using the number keys.
Mains filter	To ensure correct operation of the device, the program must be set to recognise the mains frequency adopted in the area of use. Two options are available: 50 Hz, 60 Hz.
Display	"Illumination" and "Contrast" can be set to suit the ambient conditions in which the device is used.

"Tools"

The "Tools" menu allows the user to access system related information and activate the self-test and setting functions of the device.

Options / Actions available	Description
About	Displays the version of software program installed.

Self-test	There are two self-test menus available: “User” and “Service”. Do not run the service self-test without a qualified technician in attendance. For details, see “Maintenance”.

4 Preparing for an ECG recording

This section describes the preliminary operations required when recording an at-rest electrocardiogram with the **CARDIOLINE® ar600adv** electrocardiograph. In particular, indications are given for "*connecting the patient cable*", "*preparing the patient*", "*applying the electrodes*". Also illustrated are the necessary procedures for choosing the correct recording parameters, such as "*speed, sensitivity and activation of filters*".

4.1 Connecting the patient cable

Connect the terminal plug of the patient cable to the connector identified with the symbol , positioned on the right side of the device.

Note: *to avoid breaking the patient cable, remove it from the connector gripping it by the plug, and without tugging.*

Warning: *the device is protected internally against defibrillation discharges; restoration of the signal is guaranteed as long as original protected electrodes are used. To ensure conditions of safety are always maintained, use only original accessories.*

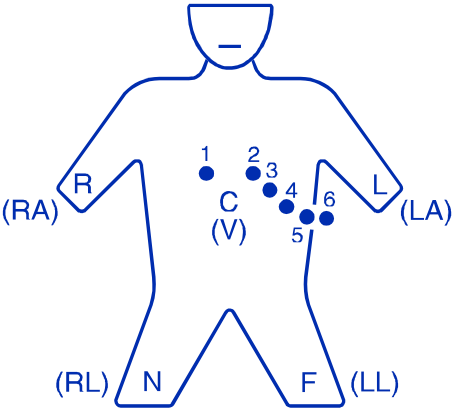
4.2 Preparing the patient and applying the electrodes

Careful preparation of the patient and correct positioning of the electrodes are fundamental in obtaining an ECG recording of high quality.

- ✓ First, make sure the patient is comfortable and relaxed and does not feel cold. The individual should lie back on a suitably large couch with arms and hands extended along the sides of the body: this will minimize the likelihood of the ECG trace being affected by muscle tremor.
- ✓ Clean the skin thoroughly with alcohol or ether at the areas where the electrodes will be placed.
- ✓ Connect each colour-coded plug of the patient cable to the respective electrode, observing the colour-position matches indicated below:

Colour	*Symbol*	*Electrode position*
Red	R	Right arm
Yellow	L	left arm
Green	F	Left leg
Black	N	Right leg
White - Red	C1	V1
White - Yellow	C2	V2
White - Green	C3	V3
White - Brown	C4	V4
White - Black	C5	V5
White - Violet	C6	V6

- ✓ Apply a small amount of electrocardiograph conductive gel to the area of the skin that will be in contact with the electrode, spreading it carefully and evenly (this is not necessary when using disposable electrodes with built-in gel).
- ✓ The following figure shows the standard positioning of the electrodes.



Standard positioning of the electrodes

V1: on the 4° intercostal space, right parasternal;

V2: on the 4° intercostal space, left parasternal;

V3: on the 5^ rib, between V2 and V4;

V4: on the 5th intercostal space, left hemiclavicular;

V5: on the left anterior axillary, same level as V4;

V6: on the left mid-axillary at the level of V4;

Peripheral electrodes: generally a few centimetres above ankles and wrists.

Warning: *make certain that the conductive parts of the electrodes are not in contact one with another or with other metallic parts. In any event, silver and silver chloride electrodes are designed and manufactured in such away as to minimize the likelihood of accidental contact between conductive parts and external metal objects. Ensure that the device is not affected by disturbances originating from the a.c. mains power supply (see* "Initial preparation"*).*

4.3 Selection of recording characteristics: operating mode, print format, speed, sensitivity, filters

Operating mode

Independently from the selected configuration operating the main menu (see "Settings"), it is possible to modify the active operational mode before every recording. The available recording modes ("Operating mode") depend on the active configuration of the electrocardiograph.

to select the desired mode; the corresponding choice is displayed on the screen.

During printing, the active mode is printed on the information line of the printout.

Print format

Independently from the selected configuration operating the main menu (see "Settings"), it is possible to modify the active print format before every recording.

-

to select the desired format; the corresponding choice is displayed on the screen.

The selected format will be applied to all manual, automatic and autotimed twelve lead recordings.

Speed of recording on paper

-
to select the speed; the corresponding value appears in the display. The options available are: 25 mm/s and 50 mm/s.

During printing, the paper transport speed is indicated on the information line.

Sensitivity of recording on paper

-
to select the sensitivity; the corresponding value appears in the display. The options available are: , 5 mm/mV, 10 mm/mV and 20 mm/mV.

During print, the recording sensitivity is indicated on the information line.

Note: *selecting the sensitivity is set automatically by the device in a way that optimizes the recording over the entire width of the paper. In this case a sensitivity of 2.5 mm/mV may be used. This option is recommended for multi-channel printing. To find out how automatic sensitivity is determined, see* "Technical Specifications".

Recording filters

If necessary, it is possible to activate filters capable of improving the legibility of the signal without modifying its morphology. Activation of the filters has an effect on the printed signal. To guarantee a correct and accurate analysis, any automatic interpretation of the trace is performed always and only on the non-filtered ECG signal.

-
to activate the filters; the corresponding symbol appears in the display. The filters available have been designed to reduce the effect of both mains disturbances and muscle tremor.

The special isoelectric anti drift filter (ADF) remains permanently activated.

During printing, the activated filters are indicated on the information line.

Important: *the filters of your ECG are very effective in attenuating disturbances and do not reduce the diagnostic content of the traces. Nonetheless, it is advisable to eliminate the cause of the interference and not only the visible effect on the trace (see* "Troubleshooting"*;* "Initial preparation"*)*

5 Recording of an ECG at rest

5.1 Patient data entry

At the beginning of each recording, in case you have choose to insert patient data, except in the case of "PC ECG" mode, the patient data management pages are displayed.

Step 1: select type of patient

- to clear data relative to the previous recording and begin a new entry.
- to display the "View" option.
- to scroll through existing data and confirm:

Esc to confirm without modification.

Step 2: enter data

The display prompts, in sequence: "Ward", "Patient ID", "First name", "Surname", "Date of birth", "Sex" or only "Date of birth" and "Sex" if you have planned the patient data entry.

- 1 … ABC 2 to enter data; a timed system positions the cursor automatically on the next character after each item is entered.
- C to clear the character highlighted by the cursor.
- to change the position of the cursor and select the "Sex" of the patient.

- to terminate the data entry step and proceed with recording.

Warning: *new data will be saved only when the final item entered is confirmed.*

5.2 Recording in manual mode

After having selected "manual" mode (see "*Operating mode*" or "Selection of recording characteristics: operating mode, print format, speed, sensitivity, filters"):

- to start the recording. If the signal has not yet been initialized, the ⚠ symbol will be displayed
- The patient data entry procedure now starts, if predict (see "*Patient data entry*").
- Pressing again the key after choosing "new patient", the recording start without entry the data patient.
- to change the leads printed during recording. The names of the active leads are indicated in the display.
- to interrupt the recording (stop).

Note: *during a manual recording, it is possible to change the recording characteristics: speed, sensitivity, filters.*

Caution: *starting a manual recording cancels the last trace recorded in automatic mode.*

5.3 Recording in automatic mode

An automatic recording allows the user to run available computation and analysis programs on the traces (" ECG measurement", " ECG interpretation" options), to obtain a copy of the recording, to save the recording ("Memory" option), and to transfer the ECG to a Computer ("PC archive" option).

After having selected "Automatic" mode (see "*Operating mode*" or "Selection of recording characteristics: operating mode, print format, speed, sensitivity, filters"):

- to start the recording. If the signal has not yet been initialized, the message "Wait …" will be displayed.
- The patient data entry procedure now starts, if predict (see "*Patient data entry*").
- During the recording, progress messages are displayed: 1. "Acquisition …"; 2. "Acquisition OK". The patient can now be disconnected.
- to interrupt printing (stop). If the signal has already been saved ("Acquisition OK") it will still be possible to print a copy of the recording.

Automatic calculation of ECG parameters

The program for automatic measurement of the ECG parameters allows a report of the principal measurements calculated to be obtained at the end of each automatic recording.

- *Start:* automatic at the end of the recording.
- *Stop:* automatic at the end of printing the report. The message "Analysis OK" is displayed.

The principal items of information in the report are:

- computed value of the following parameters: heart rate; rhythm type; P, QT, QTc, PR, QRS and QTr wave amplitudes, frontal vectors, axes.
- summary table of ST amplitudes relative to all twelve leads ;
- representative cycles of all twelve leads .

Caution: *if the measurements cannot be computed, the message "Analysis nd" is displayed. This situation may be due to excessive noise affecting the ECG trace or to incorrect positioning of the electrodes.*

Automatic ECG interpretation

The automatic ECG interpreter is a function of the analysis program that can be used to obtain an evaluation at the end of each automatic recording.

- *Start:* automatic at the end of the recording.
- *Stop:* automatic at the end of printing the report. The message "Analysis OK" is displayed.

***Warning:**. The automatic interpretation program in case of missing patient data, considers for the analysis a person of 35 years old gender male.*
***Warning:** the computerised analysis must always be validated by the medical specialist responsible for the ECG examination.*
***Warning:** if it is not possible for the device to conduct the analysis due to the poor quality of the signal, the error message "Analysis na" will appear in the display. This situation may be due to excessive noise affecting the ECG trace or to incorrect positioning of the electrodes.*

***Note:** The ECG interpreter program is structured in four parts:*

1) processing and filtering of the electrocardiographic signal

2) identification of the wave form and positioning of the markers

3) calculation of the characteristic parameters of the QRST complex

4) processing of the diagnosis and analysis of the rhythm

The part of the program "processing of the diagnosis and analysis of the rhythm", provides the evaluation of the trace, and specifically:

a) identification of the parameters that deviate from standard (these parameters are identified in the final document by an asterisk), for example, duration of P wave, lengthening of PQ interval, widening of QRS. Furthermore, the data related to the rhythm is analysed and evaluated and the related indications are given, for example sinus arrhythmia, sinus rhythm with extra ventricular systole with compensatory pause, etc. All diagnostic indications described are defined category B, in accordance with American College of Cardiology conventions.

b) analysis of repolarization changes, as internal or external, and the degree of intensity as reflected by variations in the ST-T segment. Such variations are in general correlated to an infarction or to an overload of the cardiac muscle, or even to the administration of medications. These diagnostic indications are defined category C.

c) diagnostic suggestions falling under Category A These suggestions relate to classifications such as infarction, left ventricular hypertrophy, right ventricular hypertrophy, and not least, normal trace In the HES ECG program, diagnostic suggestions belonging to category A are obtained by means of an multivariate ??? alternative classification, namely the combination of a statistical type analysis and a decisional technique of branched structure. By virtue of its characteristics and the reliability of the results provided, the EKG program is in conformity with the requirements of IEC standards pertinent to programs for the automatic ECG trace evaluation.

Copy of an automatic ECG recording

An ECG recorded in automatic mode, and computed ECG measurements if any, are memorized automatically and can therefore be reproduced on paper any number of times.

to start printing a copy. The message "Copying …" is displayed.

to interrupt printing (stop).

If the memory does not contain valid data, the message "No data" is displayed.

Note: *the trace is memorized without filtering the signal, irrespective of whether the filters are activated during the recording. The parameters can therefore be modified before printing: filters, speed and sensitivity.*

Attention:
If the "Memory Option" is not installed*: each new acquisition cancels the ECG trace memorized previously!*
If the "Memory Option" is installed: *the memorisation procedure is related to the setup. After switching off the unit, enter the archive to obtain copy of the ECG recorded.*

ECG memory: saving an ECG

An automatic ECG can be stored in archive memory. Up to 20 ECG recordings can be saved for further processing or transfer to a Personal Computer (memory option).

- *Start:* automatic, or on demand at the end of a recording (see "*Settings*").

Attention: *The message "memory full" is displayed when the memory space is closed to be completely filled. Delete or transfer examinations to the PC in order to have space free.*

ECG memory: archive management

After selecting "ECG archive":

to select the menu : 1. View; 2. PC archive; 3. Print list; 4.Empty.

to confirm the selected function.

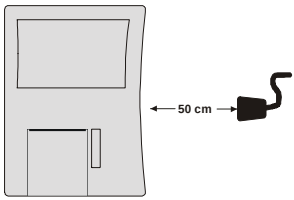
Refer to § "Archive ECG" for function's descriptions.

Saving to Personal Computer archive

Your electrocardiograph is capable of transferring stored ECG traces to a Personal Computer equipped with CARDIOLINE management software. For details on the use of the application software, consult the specific manual.

If the "Memory Option" is not installed:

- Position the electrocardiograph relative to the infrared adapter (connected previously to the PC) as illustrated in the following figure:



- to start the transfer.
- to interrupt the transfer before the end.

If the "Memory Option" is installed:

The user can either proceed as described above, if the intention is to transfer the complete ECG archive.

A detailed management of the ECG transmission can be done by using the "ECG archive" menu.

- Position the electrocardiograph as indicated previously.
- Select the "ECG archive" menu and proceed as appropriate. For details of the options available, see "*ECG archive*".

Caution: *to ensure correct data transmission, position the IR adapter of the PC at a distance of no more than one metre. Avoid placing objects between the two interfaces.*

5.4 Recording in ECG autotimer mode

Attention*: To obtain a correct recording in "ECG autotimer" mode, ensure that the battery and paper load are enough to perform the selected acquisition.*

Operating in autotimer mode, the device can make timed recordings of the 12 standard leads or of a group of three user-selectable leads.

After having selected "ECG autotimer" mode:

- to start the recording, the message "Paper, Battery!" will appear. If the signal has not yet been initialized, the message "Wait …" will be displayed.

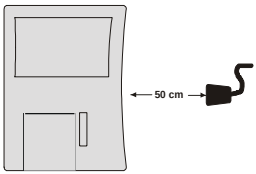
- The patient data entry procedure now starts, if predict (see "*Patient data entry*").
- Pressing again the key after choosing "new patient", the recording start without entry the data patient.
- The programmed recordings are in real time. The printouts shown information, alongside the date / time field, relating to the number of the interval and the time of recording (format: #xx yy min).
- to start a recording manually within an interval.
- to interrupt (stop).

5.5 Recording in "PC ECG" mode

Your **ar600adv** becomes a PC-based acquisition system. For details on the use of the application software, consult the specific manual.

Having selected "PC ECG" mode (see "*Operating mode*"):

- Position the electrocardiograph relative to the infrared adapter (connected previously to the PC) as illustrated in the following figure:



- to start transmission. The message "PC ECG…" is displayed.
- to end transmission.

Caution: *to ensure correct data transmission, position the IR adapter of the PC at a distance of no more than one metre. Avoid placing objects between the two interfaces.*

5.6 "Paper saving" mode

"Paper saving" mode allow to perform and store an automatic ECG recording including ECG measurements and ECG interpretation (if available) without any printout.

After selecting "Paper Saving" mode (see "Operating mode" or "Selection of recording characteristics: operating mode, print format, speed, sensitivity, filters"):

- to start the recording. If the ECG signal has not yet been initialized, the message "Wait …" will be displayed.
- The patient data entry procedure now starts, if predict (see "*Patient data entry*").
- Pressing again the key after choosing "new patient", the recording start without entry the data patient.
- During the recording, progress messages are displayed: 1. "Acquisition …"; 2. "Wait….." while the analysis is being performing (the patient can now be disconnected) 3. "Save…".
- Once the ECG has been stored it can be printed or transferred to a PC from the "ECG archive" function.

5.7 Recording in "HRV analysis mode"

***Attention**: To obtain a correct recording in "HRV analysis mode", ensure that the battery and paper load are enough to perform the selected acquisition*

A recording in HRV mode allow to analyze the measurement of the heart rate variability in a predicted interval (from 1 to 5 minutes) and to printout a complete report: full disclosure of the reference ECG lead (selected by the menu), patient data summary, table of the variability parameters (total R-R intervals, medium HR, medium R-R interval, maximum R-R interval, minimum R-R interval, ratio max/min., standard deviation, coefficient of R-R variability, number of R-R intervals greater than 2,2s and not reported on the graphic) graphic of the R-R distribution in the time domain, R-R trendgraph.

Note: connect only the electrodes related to the reference lead in order to increase the patient confort.

After selecting "HRV analysis mode":

To start the recording, the message "Paper, Battery!" will appear. If the signal has not yet been initialised, the message "Wait …" will be displayed.

The patient data entry procedure now starts, if predict (see "*Patient data entry*").

Pressing again the key after choosing "new patient", the recording start without entry the data patient.

The display shows the time from the test start. The test is automatically terminated at the end of the scheduled time and the final report is printed out.

to interrupt (stop). No report is printed and the recorded data are cancelled.

to print copy of the report at the end of the test.

5.8 Recording in "Arrhythmia mode"

***Warning**: To obtain a correct recording in "Arrhythmia mode" mode, ensure that the battery and paper load are enough to perform the selected acquisition.*

A recording in Arrhythmia mode allow to analyze in real time the ECG signal for a predicted period of time in order to detect potential abnormalities of the Rhythm in the time domain.

During the test if an abnormal rhythm is detected a printout of the events can be obtained in continuous until the rhythm become normal again (the length of the printout depends on the setup). At the end of the test, or after every 5 minutes, a complete report is printed: full disclosure of the reference ECG lead (selected by the menu) with marker identification of the abnormal beats (*), patient data summary, table of the computed parameters.

Note: connect only the electrodes related to the reference lead in order to increase the patient comfort.

After selecting "Arrhythmia mode":

To start the recording, the message "Paper, Battery!" will appear. If the signal has not yet been initialised, the message "Wait …" will be displayed.

The patient data entry procedure now starts, if predict (see "Patient data entry").

Pressing again the key after choosing "new patient", the recording start without entry the data patient.

The display shows the time from the test start. The test is automatically terminated at the end of the scheduled time and the final report is printed out (in any case every 5 minutes if the test is longer than it).

to interrupt (stop).

5.9 Defibrillation!

In the event of defibrillation, the ⚠ symbol will be displayed Within 10 seconds of the discharge, the signal is restored automatically (if the paper reproduction of the signal was activated in manual mode).

Remember always to avoid direct contact between the electrodes of the defibrillator and those of the electrocardiograph. The original approved electrodes supplied with the electrocardiograph have been designed so as to minimise the risk in case of accidental contact.

6 Management and control of electrocardiograph functionality's

6.1 Disconnected electrodes, potential defibrillation

Saturation events are controlled and monitored by your electrocardiograph. The response of the electrocardiograph depends on the current phase of operation.

Stop phase

- ✓ *Symbol* ⚠ *displayed*: critical electrode contact. The user can proceed with the recording; the "critical" electrodes are indicated in the print report on the information line (for example "⚠ L 1" indicates the critical nature of the left arm electrode and of electrode C1).
- ✓ *Symbol* ***OL*** *displayed*: electrodes disconnected (saturation). It is not possible to start an automatic recording. A manual recording can be started; the "disconnected" electrodes are indicated in the display and in the print report on the information line, and a flat signal will be reproduced on paper where a lead cannot be acquired due to the absence of an electrode (e.g. "***OL*** L 1" indicates saturation of the left arm electrode and of electrode C1).

Manual recording phase

The event is indicated as for the stop phase. When normal conditions have been restored, the signal is centred.

Automatic recording phase

If the event is detected during acquisition (10s), the ECG is stopped and automatically returns to the stop phase. If the signal is already buffered, the print continues without interruption. The event is indicated in the same way as for all other phases.

Defibrillation

The ⚠ symbol will be displayed See "*Defibrillation*".

6.2 Batteries low or in need of recharging

The batteries must be recharged when the symbol displayed is , indicating that the remaining charge is less than 30%.

Follow the indications given in the heading "*Installation and initial preparation*".

6.3 Print system control out of paper

Dedicated circuits verify the correct closure of the paper compartment cover and indicate when the thermal paper is depleted. During a recording, printout is inhibited automatically and the messages "Out of paper" or "Printer!" are displayed for 3 seconds approx.

6.4 Status messages and error indication: description and related event

Listed below are the various error messages displayed and/or printed on paper when abnormal events occur. Each message is correlated to a specific condition or phase of operation.

Messages

Message	***Description of status / event***
Not Available!	Function or action not available for the selected operating mode
Analysis nd	Automatic ECG analysis cannot be performed due to excessive signal noise
No data!	Impossible to obtain copy of the last recording
⚠	- Critical electrodes - Waiting for signal to be centred before printing can start
OL	Disconnected electrodes or potential defibrillation
Out of paper!	Paper finished, insert a new pack / roll
Printer!	Compartment cover open or not properly closed
	Batteries low
	Batteries completely discharged

6.5 Troubleshooting

The following table summarises certain problems that may occur, and the relative causes

Problem	***Cause***
Isoelectric line drift	- Use of electrodes other than originals - Use of electrodes in saturation - Insufficient electrode/skin contact - Electrode surface dirty - Patient moving

Interference from a.c. mains supply	- Voltage generator too close; presence of other clinical instruments (e.g. X-rays, etc.) - Patient in contact with metallic parts or with other persons
Muscle tremors	- Patient not relaxed - Peripheral electrodes adhering too tightly
Irregular paper transport	- End of paper roll - Paper roll incorrectly positioned - Use of non-original paper
Analysis impossible	Signal too unstable or noisy
No copy of trace	Recording interrupted before 10 seconds have elapsed
Abnormal signal	- defective patient cable - defective electrodes

7 Maintenance

7.1 Self-test

Run the User self-test procedure periodically. This performs a routine check on the functional efficiency of the display, the keys, the writing system and the memory. The user can also print out identifying information relative to the individual device.

In the event of error messages being displayed, contact the **CARDIOLINE®** Authorized Assistance Centre, and a technician will investigate and eliminate the causes of the trouble.

The self-test menu is accessed by selecting "Tools" -> "Self-test" -> "User". Before running the self-test procedure, ensure that there is paper loaded.

to select the type of test required.

to start the test.

Tests available:

- Display: pixel scan. The detection of blank areas signifies faulty operation of the display.
- Keyboard: the position of the single keys is simulated in the display. Pressing a given key, the corresponding area of the display is energized. A lack of response in any one area indicates that the relative key is faulty.
- Printer: the writing system generates two triangular waves, the character set in the memory, and signals with different speeds and sensitivities. Irregularities of the printing system are detectable in non-continuous lines.
- Memory: a message relating to the status of the memory is printed.
- About. The following items of information are printed: model identification, serial number of the device, details of software, version and language code.

Caution: *do not run the service self-test without a qualified technician in attendance.*

7.2 Replacing the thermal paper

When the thermal paper is depleted, the device stops and any attempt to start recording is inhibited (see "*Print system control. Out of paper*".)

To replace the paper, proceed as indicated in the heading "*Installation and initial preparation*".

7.3 How to clean the device and the electrodes

To clean the device, use a cloth moistened with water or denatured ethyl alcohol. Do not use other chemical products or household detergents.

For the electrodes: remove the electrodes from the patient cable and wash under running water. Do not scratch the electrodes and do not wash the leads box and the patient socket.

Note: *the device cannot be sterilized! The electrodes can be sterilized with ethylene oxide.*

7.4 How to replace the batteries

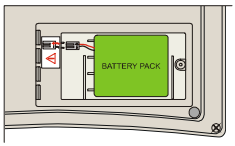
If the operation time in battery mode is considerably reduced or if it's no more possible to operate the recorder in battery mode, the batteries must be replaced.

The battery lifetime is approximately one year.

Attention: *be sure to use original batteries containing protection circuit.*

Attention*: When removing or inserting the batteries from the recorder make sure that the recorder is turned off and the A.C. power cord is disconnected from the mains, otherwise the patient and the operator may be subjected to an electrical shock.*

1. Open the battery compartment.



2. Remove the batteries taking off the connector, please remember to take note of connection polarity (red+, black-).
3. Insert the new batteries and reconnect the connector observing the polarity (red+, black-).
4. Close the batteries compartment.
5. Before using the device, refer to the recharge instruction (see § "Recharging the batteries").

6. Regulate date and hour in the corresponding menu.

***Attention**: the non-respect of the batteries connection polarity may cause serious damages to the device as well as the warranty validity failure.*

***Attention:** do not dispose of spent batteries as ordinary refuse or litter. Use only original batteries provide from the manufacturer.*

***Note**: the removal of the battery pack doesn't cause the data loss.*

7.5 Periodic checks

To ensure correct and long-lasting operation of the device, it is necessary to have an Authorized Assistance Centre carry out the following checks:

- paper drive speed calibration: every year;
- cleaning of paper compartment, paper presence sensor and writing system: every year;
- efficiency of cables and connectors: every year, by means of an ECG simulator;
- general check on functional efficiency of the device and leakage currents: every 2 years

Technical information

et medical devices SpA undertakes, when requested by qualified persons, to furnish the list of components used in the device, and the information necessary to repair the parts of the device considered serviceable.

8 Technical specifications

A.c. mains power supply	A.C. mains with external power supply 230V±10% 50/60 Hz.; available also: 115V±10% 50/60 Hz; device with power supply specified class II (second) REF type: 6308
Maximum current absorbed	100 mA at 117 V ~ ±10% 50 mA at 230 V ~ ±10%
Mains protection	Fuse: T 0.5 A
Internal power source	Set of rechargeable NiMH batteries 8x1.2 Vdc; 1500 mAh
Battery protection	PolySwitch 1.5 A - 40 °C in ambient conditions
Internal power supply protection	Pico fuse SHF SLO-BLO T 2 A Littelfuse
Applied part	CF type
Defibrillation protection	Internal
Input dynamic	± 300 mV @ 0 Hz.± 5 mV in pass band
Input impedance	> 100 MΩ on each electrode
Common mode rejection	> 100 dB
Frequency response	0,05 ÷ 150 Hz (-3dB)
Time constant	3,3 s
Acquisition	11 bit 1000 samples/s/channel printing and filters 500 samples/s/channel in calculation and filters Resolution 5 μV/bit
Leads	12 Standard or Cabrera
Signal memory	10 seconds for each lead in auto isochronous
Recording sensitivity	*manual:* 2,5 – 5 – 10 – 20 mm/mV *automatic:* dependent on number of channels printed
Writing system	Thermal printer, 8 dot/mm Usable print height 50 mm
Print channels	3
Print format	1, 2, 2+R, 3
Paper transport speed	25 - 50 mm/s
Thermal paper	*rolls* : length 15 m, gridded., page 60x75 *pack of Z-Fold* : length 18 m, page 60x75 mm, gridded.
Pacemaker recognition	Recognizes pulse in accordance with current IEC standards
Filters	*Mains interference:* Modified digital notch filter 50 - 60 Hz *Anti-drift:* digital high-pass 0.5 Hz, linear phase
Serial interface	Infrared
Keyboard	Membrane, with functional and alphanumeric keyboard semplified
Interpretation program	*Parameter calculation* (optional) *ECG interpreter* (optional
Type of use	Continuous

Operating modes	*manual:* acquisition and printing in real time *automatic* : simultaneous acquisition *timed:* acquisition at user-defined intervals *PC-ECG:* real time acquisition with display at PC *Paper Saving*: Automatic acquisition and archiving without printing *Arrhythmia*: analyse in real time arrhythmic phenomenons with recording in continuous HRV: heart rate variability analysis
Capacity	*Internal battery:* 3 hours in 1 channel mode
Recharging time	*Internal battery:* 14 hours 100%
Housing protection category	IP 20
Ambient conditions: - operation - transport and storage	 *Ambient temperature:* da +10°C a +40°C *Relative humidity:* da 25% a 95% (without condensation) *Atmospheric pressure:* from 700hPa to 1060 hPa *Ambient temperature:* from -10°C to +40°C *Relative humidity:* from 10% to 95% (without condensation) *Atmospheric pressure:* from 500 to 1060 hPa
Dimensions	250 x 60 x 185 mm (length x height x depth)
Weight	1000 grams without paper
Conformity to standards	EN 60601-1: 1990 EN 60601-1/A1: 1992 EN 60601-1/A2: 1995 EN 60601-1/A13: 1995 *General standards for safety of electromedical equipment* EN 60601-1-2: 1993 *Standards on electromagnetic compatibility of electromedical equipment* EN 60601-2-25: 1995 *Particular safety standards for electrocardiographs* EN 60601-2-51/Ed.1: 2001 *Particular standards on essential recording and analysis performance safety of single and multichannel electrocardiographs.*

Basic accessories supplied

- patient cable cod. 63050025
- 6 suction cup electrodes cod. 63030108
- 4 peripheral electrodes cod. 63030105
- bottle gel (260 ml) cod.66020002
- 1 pack paper 60mm x 20m cod. 66010040
- 1 roll paper 60mm x 15m cod. 66010037
- frequency count gauge
- ECG carrying bag
- user manual

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